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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,314	11/18/2003	John M. Stewart	P26,473-A USA	7296
23307	7590	10/31/2006		
SYNNESTVEDT & LECHNER, LLP 2600 ARAMARK TOWER 1101 MARKET STREET PHILADELPHIA, PA 191072950				
EXAMINER ROOKE, AGNES BEATA				
ART UNIT			PAPER NUMBER	
1656				

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/716,314	Applicant(s) STEWART ET AL.	
	Examiner Agnes B. Rooke	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 10-13, 22-26 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 2-5, 10-13, 22-26 and 28-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The Restriction requirement sent on 10/02/2006 is withdrawn and it is replaced with the instant office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-5, 10-13, 30, and 31, drawn to a peptide of SEQ ID NO:2 and its pharmaceutical composition, classified in class 530, subclass 350.
- II. Claim 22, drawn to a method of treatment of migraine with SEQ ID NO:2, classified in class 514, subclass 12.
- III. Claims 23, 24, and 32, drawn to a method of providing analgesia by administering SEQ ID NO:2, classified in class 514, subclass 12.
- IV. Claims 25 and 33, drawn to a method of reducing wrinkles by administering SEQ ID NO:2, classified in class 514, subclass 12.
- V. Claim 26, drawn to an antibody, classified in class 530, subclass 387.1.
- VI. Claims 28 and 29, drawn to a nucleic acid encoding SEQ ID NO:2, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

The protein of invention I is related to the antibody of invention V by virtue of being the cognate antigen necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used in another and materially

different process from the use for the production of the antibody, such as in a pharmaceutical composition, or to assay or purify the natural ligand of the protein, or in assays for the identification of agonists or antagonists of the receptor protein. Therefore, the inventions are distinct.

The protein of invention I and nucleic acid of invention VI are patently distinct inventions for the following reasons. Proteins, which are composed of amino acids, and nucleic acids, which are composed of purine and pyrimidine units, are structurally distinct molecules. In the present invention, the nucleic acid of invention VI does not necessarily encode the protein of invention I. Also, the information provided by the nucleic acid of invention VI can be used to make a materially different protein than that of invention I. Moreover, the proteins of invention I can be recovered from a natural source using biochemical means, such as affinity chromatography. Therefore, the inventions are distinct.

The nucleic acid of invention VI and the antibody of invention V are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are different compounds having different compositions and functions. Therefore, the inventions are distinct.

Invention I and inventions II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, the protein of invention I, can be used in different methods as described in inventions II-IV. Therefore, the inventions are distinct.

Invention V and inventions II-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibody of Invention V cannot be used in methods of inventions II-IV. Therefore, the inventions are distinct.

Invention VI and inventions II-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acid of invention VI cannot be used in inventions II-IV. Therefore, the inventions are distinct.

Inventions II-IV are related by virtue of the protein that is used in all the claimed methods. However, inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each method is distinct from each other because they perform distinct functions, and have different modes of operation regarding different methods of use or methods of treatment. Therefore, the inventions are distinct.

Because the inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for the examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. or call 866-217-9197.



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER



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